HFE-35
M2179N

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

6751 Steger Drive
Cincinnati, OH 45237-3097

WARNING LETTER

November 6, 1998

Cin-WL-99-39

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Talmadge V. Hays, M.D.
Controlling Partner
Total Care Clinic
121 Virginia Ave.
Pineville, KY 40977

Facility ID# 162321

Dear Dr. Hays:

Your facility was inspected on October 20 & 21, 1998 by a representative from the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

900.12(d)(2) 1. The phantom image score for the masses was 1.5, and this did not meet the required minimum masses score of 3.0.

This specific problem appeared on your MQSA Facility Inspection Report that was issued to your facility at the close of the inspection. This problem is identified as Level 1, because the problem identifies a failure to meet a significant MQSA requirement.

In addition, there were other noncompliance issues that were listed as Level 2, as noted in the inspection report that was provided to your facility:

900.12(d)(2) 2. The number of speck groups scored in the phantom radiographic image did not meet the minimum requirements. The score was 2.0. The minimum number required for speck groups is 3.0.

900.12(d)(2) 3. The number of fibrils scored in the phantom radiographic image did not meet the minimum requirements. The score was 3.0. The minimum number required for fibrils is 4.0.

900.12(d)(1) 4. Mammograms were processed for 20 days in September 1998 and at least 11 days in October 1998 without the required daily quality control processor testing being performed.

Also the inspection revealed the following "Level 3" noncompliance items relating to quality assurance for mammography:

900.12(d)(5) 5. Corrective actions were not conducted based on the recommendations indicated in the December 4, 1997, medical physicist's annual survey report and the January 10, 1998, medical physicist's follow up survey report.

900.12(d)(2) 6. The required monthly phantom image tests were not performed in the months of September and October 1998.

900.12(d)(2) 7. There was no documentation of the typical patient clinical settings for the phantom image tests during the months of October 1997 through August 1998.

900.12(d)(3) 8. There was no calculation performed for evaluation of the repeat analysis procedure.

900.12(d)(1) 9. The darkroom fog was measured at the fog level of 0.07 exceeding the maximum allowable fog limit of 0.05.

900.12(d)(1) 10. The mammography technique tables/charts were not updated.

While not specifically mentioned in your inspection report, the inspector evaluated your facility's QC phantom images. Two of the images had net a score of 1. 5 masses for the January 1998 and July 1998 images. For item five above, the medical physicist indicated in his December 4, 1997 report that your facility had failed the phantom image as a result of the grid artifact. Also mentioned in the annual medical physicist report in his Recommendations of Quality Improvement section, he stated "This unit does not perform in state-of-the-art fashion. Its continued use for mammography is problematical. Consideration should be given to replacing the unit in the near future, or else the facility should cease performing mammography."

In the January 10, 1998 medical physicist's follow up survey report, he indicated that the average glandular dose rates were corrected; but the report stated the following: "Reducing the dose to that level on your machine would result in images that clinically unacceptable."

In discussion with [redacted], mammography technologist of your facility, she stated that the mammography service representative revealed to her that the parts (grid and x-ray tube) cannot be obtained because the unit is too old. Your facility failed to follow the medical physicist's recommendations.

Ms. [redacted] stated your facility attempted to be reaccredited with the American College of Radiology (ACT) in the Summer, 1998 by submitting part one of the ACT reaccreditation application and part two containing a set of the ACT requested clinical images. Subsequent to the submission of the first set of clinical images, ACR contacted your facility, ACR indicated to your facility that the first set of clinical images failed the ACR review. Ms. [redacted] indicated your facility made no attempt to submit a second set of clinical images to ACR.

Because these conditions are symptomatic of serious underlying problems that compromise the quality of mammography at your facility, they represent a violation of the law, which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date of receipt of this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records.

We have discussed these findings from your MQSA inspection with your accreditation body, the American College of Radiology. After an assessment of the serious problems

currently present at your facility, FDA has determined that the quality of mammography may have been severely affected by these conditions. Therefore, we request that you undergo Additional Mammography Review (AMR) by the ACR. Since we have evidence that image quality problems may extend back to January 10, 1998 (the date of the last medical physicist report), the image quality may have been affected from this date to October 19, 1998. Therefore, we believe that the AMR should cover the time frame from January 10, 1998 to October 19, 1998.

The ACR are aware of our request that you undergo an AMR. Your facility is responsible for the payment of the costs to the accreditation body for the AMR. The accreditation body may require a portion or all of this payment prior to the start of the AMR. You should contact the following individual at the ACR for more information on the AMR at your facility:

Pamela A. Wilcox-Buchalla, R.N., M.B.A.
Director, Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091

Once the AMR has been completed, the ACR will submit a detailed report of the review to the FDA and we will provide you with a copy at that time. This report would usually include the total number of examinations evaluated by the physician(s), a list of examinations with films showing image quality problems that may need to be repeated, and an overall assessment by the reviewing physician(s) of the quality of mammography from January 10, 1998 to October 19, 1998.

If the AMR indicates that clinical image problems exist that represent a serious risk to health, FDA may request that your facility submit a proposed plan for patient notification, including draft letters to referring physicians and/or patients. The draft letters will be subject to approval by the FDA.

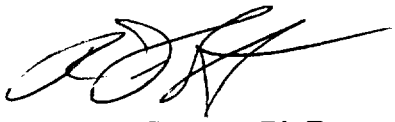
Please submit your response to:

Mr. R. Terry Bolen
MQSA Radiological Health Officer,
Food and Drug Administration
6751 Steger Drive.
Cincinnati, OH 45237-3097.
513-679-2700 x138; FAX: 513-679-2772

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact: Mr. R. Terry Bolen, MQSA Radiological Health Officer, 513-679-2700 x138.

Sincerely yours,



R. Duane Satzger, Ph.D.
Acting District Director
Cincinnati District Office

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ACR

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